K120409

510(K) Summary

CarboFix Orthopedics Ltd. Piccolo Composite™ Plate System

NOV 26 2012

Applicant Name

CarboFix Orthopedics, Ltd.
11 Ha'hoshlim St., Herzeliya 46724, Israel

Contact Person

Yael Rubin
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Date Prepared

April 2012

Trade/Proprietary Name

Piccolo Composite™ Plate System

Common Name

Bone Plating System

Classification Name

Single/multiple component metallic bone fixation appliances and accessories; (21 CFR §888.3030; Class II; Product Code HRS, KTT).

Predicate Devices

- Piccolo Composite™ Plate System (CarboFix Orthopedics Ltd.; K102597)
- Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates (Synthes; K073460)
- Synthes One Third Tubular LCP Plate (Synthes; K011335)
- VariAx™ Distal Fibula Plate and Fibula Straight Plates (Stryker (Howmedica Osteonics Corp.); K081284)
- SPS Small Fragment Set (Stryker (Howmedica Osteonics Corp.); K000636)
- Mini Variable System (OrthoHelix Surgical Designs, Inc.; K111041)

Indications for Use

Piccolo Composite™ Distal Fibula Plate System

The Piccolo Composite™ Distal Fibula Plates are indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula, including in osteopenic bone.

Piccolo Composite™ One-Third Tubular Plate System

The Piccolo Composite™ One-Third Tubular Plates are indicated for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, radius, ulna, pelvis, and fibula including in osteopenic bone.

Piccolo Composite™ Proximal Humerus Plate System

The Piccolo Composite™ Proximal Humerus Plate is indicated for fractures, fracture dislocations, osteotomies, and nonunions of the proximal humerus, including in osteopenic bone.

Piccolo Composite™ Distal Volar Radius Plate System

The Piccolo Composite™ Distal Volar Radius Plate is indicated for fractures and osteotomies of the distal volar radius.

System Description

The Piccolo Composite™ Distal Fibula and One Third Tubular Plate Systems comprise implants (plates and screws), and sets of instruments.

The Plates are made of carbon fiber reinforced polyetheretherketone (CFR-PEEK), and are marked with a tantalum thread, to provide for their visualization under fluoroscopy.

The Screws are made of titanium alloy. Both non-locking screws and locking screws are available, in various dimensions.

The general description of the Piccolo Composite™ Proximal Humerus and Distal Volar Radius Plate Systems is not changed as compared to the predicates.

Substantial Equivalence

The Piccolo Composite™ Plate System intended use, design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.

Performance characteristics for the Piccolo Composite™ Distal Fibula and One Third Tubular Plate Systems, such as single cycle (static) 4-point bending and dynamic (fatigue) 4-point bending, were evaluated per ASTM F 382 – Standard Specification and Test Method for Metallic Bone Plates and are comparable to those of predicate devices (where applicable). Axial static and dynamic bending tests, selected screws characteristics evaluation, and evaluation in support of the MR Conditional labeling parameters were also provided. All the above demonstrate that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 26, 2012

CarboFix Orthopedics, Limited
% Mr. Yael Rubin
Director of Regulatory Affairs
11 Ha'hoshlim Street
Herzeliya, Israel 46724

Re: K120409
Trade/Device Name: Piccolo Composite™ Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, KTT
Dated: November 20, 2012
Received: November 23, 2012

Dear Mr. Rubin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K120409

Device Name: Piccolo Composite™ Plate System

Indications for Use:

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Piccolo Composite™ One-Third Tubular Plate System

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Piccolo Composite™ Distal Volar Radius Plate System

The Piccolo Composite™ Distal Volar Radius Plate is indicated for fractures and osteotomies of the distal volar radius.

Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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